Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Telephone: 847.680.1000
Facsimile: 847.918.3860

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Hollister Incorporated
InCare Pelvic Floor Therapy System

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
Ph : (847) 680-2849
Fax: (847) 918-3860

Date Summary Prepared – November 2, 2001

2. Name of Device:

InCare Pelvic Floor Therapy System.

3. Name of Predicate Device(s)

1. InCare Pelvic Floor Therapy Systems K930530/c, K961872, and K974048
2. Elpha 2000 Conti Device, K964738

4. Description of Device

The InCare Pelvic Floor Therapy System is an office based instrument that is intended to be used by physicians, nurses, nurse clinicians, and physiotherapists in a physicians office, clinic, or hospital for the purpose of providing electromyography or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and the restoration of neuromuscular control for the treatment of urinary incontinence.

The InCare Pelvic Floor Therapy System also provides electrical stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence.

5. Statement of Intended Use

The electrical stimulation component of the InCare Pelvic Floor Therapy System provides stimulation capabilities that are intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence.

The biofeedback components of the InCare Pelvic Floor Therapy System are intended to provide electromyography or pressure biofeedback from the pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of urinary incontinence.

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InCare Pelvic Floor Therapy System

6. Statement of Technological Characteristics of the Device

The proposed InCare Pelvic Floor Therapy System is an office based instrument that is intended to be used by physicians, nurses, nurse clinicians, and physiotherapists in a physicians office, clinic, or hospital for the purpose of providing electromyography or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and the restoration of neuromuscular control for the treatment of urinary incontinence. The InCare Pelvic Floor Therapy System also provides electrical stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence.

The proposed InCare Pelvic Floor Therapy System is comprised of a combination of an instrumentation unit and a personal computer. Other peripheral devices such as monitors and printers can be added for convenience or ease of use. The personal computer and instrumentation unit are physically separate devices "linked" to each other by a communication pathway. Features or functions that are "data manipulation and presentation" activities are properly associated with the personal computer. Features or functions that are" patient therapy" actions are controlled by the instrumentation unit.

7. Conclusion

Based upon the information presented within this pre-market notification it is concluded that the proposed InCare Pelvic Floor Therapy System with expanded stimulation parameter of 10 Hz and updated clinician application software is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2002

Mr. Joseph S. Tokarz
Manager Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048-3781

Re: K013612
Trade/Device Name: InCare PRS9500 Pelvic Floor Therapy System
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Product Code: 78 KPI
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Product Code: 85 HIR
Regulatory Class: II
Dated: February 13, 2002
Received: February 27, 2002

Dear Mr. Tokarz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Hollister Incorporated
InCare Pelvic Floor Therapy System

Statement of Intended Use

510(k) Number (if Known): K013612

Device Name: InCare Pelvic Floor Therapy Stimulation/Biofeedback Device

Indications For Use:

The electrical stimulation component of the InCare Pelvic Floor Therapy System provides stimulation capabilities that are intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence.

The biofeedback components of the InCare Pelvic Floor Therapy System are intended to provide electromyography or pressure biofeedback from the pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of urinary incontinence.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lagergren

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013612